

Policy Number: 35

Title: Policy for the Role of a Witness and/or Participant Advocate

Date of Last Revision: 05/13/2008; 06/16/2010; 02/26/2020

Policy:

The UCI Institutional Review Board (IRB) has the authority to observe or have a third party (i.e., an impartial witness) observe the consent process or to require a participant advocate to act as a liaison between an Investigator and a research participant, the participant's family, or a participant's legally authorized representative.

When meeting the requirement to attest that informed consent to the California Medical Experiment Act have been satisfied, the consent form is signed and dated by any person other than the subject or the subject's guardian or legally authorized representative who can attest that the requirements for informed consent has been met, as specified in Section 24175 of the California Health and Safety Code. At UCI, the investigator's signature serves this purpose and an impartial witness is not required (see Procedure 35 A I).

- I. Observation of the consent process by a third party also called a witness *is required* in the following situations:
 - A. When using the foreign language short form process for participants who do not speak English;
 - B. When obtaining informed consent from a participant (or the participant's guardian or legally authorized representative) who can understand and comprehend the language, but is physically unable to talk or write. The participant can be entered into a study if they are competent and able to indicate approval or disapproval by other means.
 - C. When obtaining informed consent from a participant (or the participant's guardian or legally authorized representative) who can speak but is unable to read or write.
 - D. When obtaining informed consent from a participant (or the participant's guardian or legally authorized representative) who is blind.

- II. The IRB may determine that additional protections such as observation of the consent process by an impartial witness or the involvement of a participant advocate in the consent process or throughout the course of the research study are necessary when the research:
 - A. Involves high risk to special or vulnerable populations (cognitively impaired individuals, children, prisoners, adults unable to read);
 - B. Methodology or procedures are ethically sensitive (e.g., donation of embryos for stem cell research); and/or
 - C. Is conducted by researcher who previously has failed to comply with the requirements of the Department of Health and Human Services (DHHS) regulations

- D. Involves any other situation determined by the IRB to require additional protections.
- III. Witness Role
- A. The role of a witness is to observe the consent process in situations required per Federal and State regulations, per UCI IRB policy or per the determination of the IRB.
 - B. The witness should remain unbiased regarding the research and the participants. Their role is to assure the conduct of legally effective informed consent.
 - C. The role of the witness may be served by a member of the IRB or may be an impartial third party. A witness must be an adult who is not a member of the study team (i.e., is not listed on the protocol narrative) and who is not a family member of the participant.
 - a. Short Form Consent Process: In cases where the interpreter or translator is an impartial third party to an oral / IRB approved short form consent process but is not physically present (e.g., a virtual consent process), the family member of the participant may be allowed to serve as a witness. The family member serving as a witness must be fluent in both English and the language of the participant. The witness must sign and date both the short form written informed consent document and a copy of the IRB approved English version of the consent document.
 - D. The IRB Committee may require that the Investigator obtain an impartial witness or the IRB may appoint an impartial witness.
- IV. Participant Advocate Role.
- A. As determined by the IRB, the role of a participant advocate is to assure that the participant receives equitable and ethical treatment during the informed consent process and/or throughout the course of the research study. The advocate could be a single person with an interest in the population studied or a group of people interested in the safety of human research participants, usually within a certain population (e.g., breast cancer patients, patients with schizophrenia, etc.).
 - B. The IRB Committee may require, at their discretion, that the Investigator use a participant advocate or provide an advocacy group as a contact to the participants. Moreover, the IRB may appoint a specific participant advocate.

References:

The Belmont Report

45 CFR 46

21 CFR 50

California Health and Safety Code 24170-24179.5

FDA Information Sheets: Frequently Asked Questions: Informed Consent Process, A Guide to Informed Consent

Guideline for Good Clinical Practice: <http://www.ich.org/LOB/media/MEDIA482.pdf>

Procedure Number: 35.A

Title: Procedure for the Role of a Witness and/or Participant Advocate

Procedure:

This procedure outlines the process for the use of an impartial witness or a participant advocate in assisting the UCI Institutional Review Board (IRB) in the protection of human research participants.

- I. Investigator's Responsibilities.
 - A. To obtain an impartial witness to observe the consent form process when federal and state regulations apply to the research (see IRB Policy 35, Item I).
 - B. To obtain an impartial witness to observe the informed consent process, per the authority of the IRB.
 - C. To utilize a participant advocate, to assist in the informed consent process and/or oversee the research process in studies where the IRB determined such oversight was required.
 - D. When meeting the requirement to attest that informed consent to the California Medical Experiment Act has been satisfied, the consent form is signed and dated by any person other than the subject or the subject's guardian or legally authorized representative who can attest that the requirements for informed consent have been met. At UCI, the investigator's signature serves this purpose and an impartial witness is not required.

- II. IRB Committee Responsibilities.
 - A. It is the responsibility of the IRB Committees to determine whether an impartial witness, participant advocate or advocacy group are necessary when the research:
 1. Involves high risk to special or vulnerable populations (cognitively impaired individuals, children, prisoners, adults unable to read);
 2. Methodology or procedures are ethically sensitive (e.g., donation of embryos for stem cell research); and/or
 3. Is conducted by researcher who previously has failed to comply with the requirements of the Department of Health and Human Services (DHHS) regulations
 4. Involves any other situation determined by the IRB to require additional protections.
 - B. The IRB Committee may determined that the impartial witness observe the consent process or a participant advocate be involved in specific activities associated with the research, e.g. the informed consent process or throughout the course of the research study.

- III. IRB Administrator Responsibilities.
 - A. The Administrator will conduct a pre-review of the study application and informed consent documents submitted with a new study application to determine the vulnerability of the research participants or the potential for vulnerability of the targeted population. If more information is needed

regarding additional protections for inclusion of a vulnerable population, the informed consent process or documentation, the Administrator will contact the Investigator and request the additional information.

- B. The Administrator will assure the informed consent document contains the proper language for the use of an impartial witness or participant advocate, if applicable.
- C. The Administrator will assist the Investigator in the appointment of an advocate, an advocacy group or an impartial witness, if deemed appropriate by the IRB Committee or requested by the Investigator.